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FACSIMILE COVER SHEET**Examiner:** Alexander H. Spiegler**FAX No.:** 703-308-4242**Group Art Unit:** 1637**Date:** 1 November 2002**From:** Gary D. Colby**FAX Operator:** Gary D. Colby**Re:** U.S. Patent Application Serial No. 09/826,522**Title of Paper sent via Facsimile:** 1) Response to Restriction Requirement and Preliminary

Amendment (11 pages)

2) Marked-Up Copy of Claim Amended (1 page)

3) Clean Copy of Claims, as Amended (7 pages)

Time: 3:00**Akin Gump File No:** 210691.0001/1US**Page 1 of 20** pages

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PATENT
BOX-NON-FEE AMENDMENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re	: Patent Application of	: Group Art Unit: 1645
	: John R. DePhillipo <i>et al.</i>	
	:	
Conf. No.:	: 2835	: Examiner:
	:	: Alexander H. Spiegler
	:	
Appln. No.	: 09/826,522	:
	:	
Filed	: April 5, 2001	: Attorney Docket No.
	:	: 10691-1
For	: KITS AND METHODS FOR ASSESSING	:
	: OXIDATIVE STRESS	:

**RESPONSE TO RESTRICTION REQUIREMENT
AND
PRELIMINARY AMENDMENT**

This paper is filed in response to the Restriction Requirement dated 2 October 2002 (Paper No. 5). This paper includes both a Response to the Restriction Requirement and a corresponding Preliminary Amendment, which the Applicants request the Examiner to enter.

Response to Restriction Requirement

In the Restriction Requirement, the Examiner identified three Groups of claims, designated Groups I-III. The Applicants elect the claims of **Group II** (claim 39). This election is made without traverse.

In the Restriction Requirement, the Examiner indicated that if the claims of Group I or III were elected, then the Applicants would also be required to elect one pair of the genes listed in claim 6. This requirement was not applied to Group II. The Applicants believe that non-application of this requirement to the claims of Group II was an oversight on the part of the Examiner, because the recitations of claim 39 substantially mirror those of claim 1. Nonetheless, the Applicants believe that the requirement that two genes be selected should not be applied to the elected claims.

The Applicants believe that the Examiner does not fully appreciate the subject matter that the Applicants have invented. At least two aspects of the subject matter of the elected

claims are relevant to whether the Applicants should be required to select only two genes for prosecution on the merits. These two aspects are described in the following paragraphs.

First, the Applicants have identified a set of genes that are informative for susceptibility of an individual to oxidative stress. Thus, the Applicants have discovered that it is occurrence of certain polymorphisms in these genes (i.e., not necessarily others) that should be assessed, and that the more of these genes that are assessed, the more complete the overall assessment of oxidative stress will be.

Second, the Applicants have discovered that the polymorphisms of these genes that are informative are not necessarily associated with oxidative stress disorders. Any "disorder-associated polymorphism" (the term recited in the claim) in one of the genes in the identified set is informative with regard to the patient's overall state of oxidative stress. The identity of the disorder with which the polymorphism is associated is not important.

The Applicants believe that application of the restriction requirement discussed in item 2 of Paper No. 5 (i.e., restriction to only two genes) is not an appropriate way to search or examine the subject matter that the Applicants have invented because the Applicants have not merely discovered discrete associations between oxidative stress and individual genes or polymorphisms. Instead, the Applicants have discovered an association between susceptibility to oxidative stress and i) a class of polymorphisms (i.e., "disorder-associated" ones, regardless of the disorder) in ii) certain types of genes (i.e., those designated a-e in claim 39, as exemplified by genes i-xxvii in claim 62). Imposition of the restriction requirement discussed in item 2 of Paper No. 5 would therefore artificially restrict the invention to only an arbitrary portion of the overall invention that the Applicants have made. The Applicants request that the Examiner not impose the restriction requirement discussed in item 2 of Paper No. 5 to newly added claims 58-94.

To the extent the restriction requirement discussed in item 2 of Paper No. 5 can be considered a request by the Examiner for guidance regarding how a search of the prior art might be conducted, the Applicants believe that it may be possible to identify some of the closest prior art by narrowing the Examiner's search, at least initially, to the genes numbered i-iv in claim 60. Of course, the Applicants do not have encyclopedic knowledge of the prior art, and the Examiner is urged to conduct the prior art search in the manner thought best by him.